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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,062	06/06/2001	Steven M. Ruben	PT033P1	6884
22195	7590	12/29/2003	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			MITRA, RITA	
		ART UNIT		PAPER NUMBER
				1653

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,062	RUBEN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12, 13 and 23-42 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) Other: _____ .

DETAILED ACTION

Status of the Claims

Applicants' preliminary amendment and provisional election filed on November 3, 2003 is acknowledged. Claims 1-11 and 14-22 have been canceled. New claims 23-42 have been added. Claims 12 and 13 are withdrawn from consideration because they are non-elected claims. Therefore, claims 23-42 are currently pending and are under examination.

Election/Restriction

Applicants' election with traverse of Group I represented by original claims 1-10, 14 and 15 (now canceled), and new claims 23-42, drawn to polynucleotides having SEQ ID NO: 2 sequence, encoding SEQ ID NO: 3, and the cDNA clone HWHQC55 in ATCC deposit NO. PTA1009 filed on November 3, 2003, is acknowledged. The traversal is on the ground that even where patentably distinct inventions appear in a single application, restriction remains improper unless the examiner can show that the search and examination of these groups would entail a "serious burden." The traversal is also on the ground(s) that separate and diverse searches of groups I-IX directed to nucleic acids set forth in SEQ ID NO: 2; polypeptides set forth in SEQ ID NO: 3; antibody; method for gene therapy using polynucleotides and polypeptides; method for diagnosing pathological conditions related to polynucleotides and polypeptides; method for identifying a binding partner to polypeptide; method of screening for molecules that modify activities of the polypeptides, would not be required. Applicants submit at pages 5-6 that with respect to a given sequence, a search of the claims of the groups directed to that sequence would also provide useful information for the claims of the other groups directed to that sequence, for example, in many if not most publications disclosing a protein, the authors also disclose nucleic acids encoding the protein, antibodies to the protein, and methods of making and using the same. This is not found persuasive because a search of the polynucleotide claims would not and does not necessarily encompass claims directed to methods for selecting a compound which modulates the response induced by polypeptides; an antibody capable of binding to polypeptides. The prior art pertaining to these patentably distinct subject areas is vastly different. For example,

many publications provide no sequence data at all making it difficult if not impossible to establish a link between a given polynucleotide sequence and a corresponding polypeptide or related methods, therapies and antibodies. It would constitute an undue burden to search claims directed to the polynucleotides along with the distinct inventions of the polypeptides and antibodies. For example, the prior art is replete with examples of proteins, which have been isolated and purified, but only much later sequenced and the corresponding cDNA cloned, but yet have not disclosed antibody. Therefore, on its face, a search of the polynucleotide claims would not encompass claims to the methods using the polypeptides for identification of compounds and antibodies selective for the polypeptide, etc. Consequently, a search of claims directed to these patentably distinct groups together would constitute an undue burden.

At page 5 Applicants urge that the search of all groups would not entail a serious search burden on the Examiner and therefore, the restriction is improper. The groups are directed to different subject matter as shown by different classification set forth in the prior office action. Therefore, examination of all groups would present a serious search burden, thus the restriction requirement is maintained.

Applicants submit (page 5) that searches for proteins, nucleic acids encoding such proteins, antibodies to such proteins, and methods of making and using the same commonly overlap. The inventions of nucleic acids, proteins and antibodies are distinct and differ by physical, chemical and biological function. A search for a protein product requires a search covering class 530/350, 300+, whereas a search for the recombinant production of the protein requires a search that covers 435/69.1, 252.3, 320.1, 325 and 536/23.5. Therefore, the search for section I and II does not overlap and constitute different searches.

Applicants have requested (page 6) that upon indication of allowable subject matter, the Examiner rejoin the claims of group I with process claims of groups IV and V.

In response the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)*,” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement is still deemed proper and is therefore made **FINAL**.

In view of the foregoing, claims 12 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 23-42, SEQ ID NO: 2 and 3; Gene 1 (HWHQC55) are examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 23-42 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides and polypeptides encoded thereby are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed, nor any art of record discloses or suggests any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on page 10 (gene 1) and page 12 (Table 1) describes clone HWHQC55 (ATCC NO: PTA1009) to which the instant invention relates. The specification indicates at page 10 that translation products corresponding to this gene share sequence homology with the serine 2 ultra high sulfur protein. However, specification has not provided the sequence homology or describe any biological activity which is similar to serine 2 ultra high sulfur protein. The specification also asserts (page 11) that polynucleotides and polypeptides of the invention are useful as reagents for differential identification of epithelial tissues or cell types present in a biological sample and for diagnosis of diseases and conditions, which include diseases and disorders of the epithelium, skin and hair. Further specification indicates that for a number of disorders of the tissues or cells, particularly of the epithelium, skin and hair, expression of this gene may be routinely detected, relative to the standard gene expression level, i.e., the expression level in healthy tissue or cell. However, the specification fails to provide any description of how to use such tissue or cells for expression or how such expression would have been assessed. In this regard, it is noted that pages 10-12 refer to various tests and diseases, but there is no explanation of, e.g., how or what would have been affected by the gene, or how one would have used such information gleaned from expression or data from any tests or assays. For example, the specification asserts that expression in healing groin wound and fetal epithelium tissues and

homology to serine 2ultra high sulfur protein, indicates that polynucleotides and polypeptides corresponding to this gene are useful for the detection, and/or treatment of diseases and /or disorders of the epithelium, skin and hair, including regenerative and developmental disorders of the epithelium skin and hair.

Based on the specification (pages 10-12), neither any biological activity has been set forth for the polynucleotide and polypeptide encoded thereby of clone HWHQC55 nor has any use for the polypeptide itself been provided. Only speculative biological activities have been provided on page 86-98 and 134-196 of the specification. In examples 1-17, it appears that these experiments have not been performed. The examples are not written in the past tense. Therefore, they appear to be prophetic examples ((MPEP 608.01 (p)). For example, the use of the protein for further research is described here (page 94-98). This use is not a patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed proteins. This situation requires carrying out future research to identify or reasonably confirm a “real world” context of use and therefore does not define specific and substantial utility.

The specification at page 209 indicates that the polynucleotides or polypeptides can be used as a nutritional source of polynucleotides. This use is considered to be a “throw away” utility and does not distinguish the claimed polynucleotide over any other polynucleotide. The utility is not specific or substantial.

Other activities that the protein is asserted to exhibit are listed throughout page 207-209 of the specification. However, these activities are speculative. In summary, the polynucleotides and encoded proteins claimed do not have a credible, specific or well-established or even demonstrable utility and therefore lacks utility under 35 U.S.C. 101.

Claim 23, 24 and 25 drawn to an isolated nucleic acid comprising a polynucleotide selected from the group consisting of a polynucleotide encoding amino acid residues 1-230 of SEQ ID NO: 3 and polynucleotides comprising nucleotides 1-1101 of SEQ ID NO: 2. The specification does not describe the functional properties of the polynucleotides and entire full-length protein or its mature form encoded thereby, and the structural information is limited (see next paragraphs). While the specification enumerates several known assays for biological

activity (p. 98-106, Examples 17), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed polynucleotides and polypeptides encoded thereby, for which no known activity is explicitly disclosed nor demonstrated.

Claims 26 and 27 drawn to a nucleic acid of claims 23 and 26 respectively, which comprises a heterologous polynucleotides and heterologous polypeptide sequence respectively. It is not clear from the description on page 38-39 (Example 9) what is the heterologous protein's structure, and /or its function.

Claims 28, 29, 30, 31 and 32 are drawn to a vector and a recombinant host cell comprising the isolated nucleic acid molecule of claim 23, wherein the nucleic acid molecule is operably associated with a heterologous regulatory sequence that controls gene expression, a method for producing polypeptide by the method comprising expressing the polypeptide by a cell and recovering the polypeptide. Specification on page 39-43 describes the vectors and host cells but does not indicate the function of the expressed protein.

Claims 33, 34 and 35 are drawn to a polynucleotide encoding the amino acid sequence of the full length polypeptide encoded by the cDNA clone contained in HWHQC55 in ATCC Deposit No. PTA1009, and a polynucleotide comprising the cDNA clone contained in HWHQC55 in ATCC Deposit No. PTA1009. It is not clear from the description of the clone (specification page 10-12) about the protein structure, aside from its amino acid sequence, and/or its function. As discussed above, based on the specification (page 10-12, 86-98) it is unclear what activity the claimed polynucleotides and the polypeptides encoded thereby possess or how a person having skill in the art would have used the claimed polynucleotides and the polypeptides encoded thereby.

Claims 36 and 37 drawn to a nucleic acid of claims 33and 36 respectively, which comprises a heterologous polynucleotide and heterologous polypeptide sequence respectively. It is not clear from the description on page 38-39 (Example 9) what is the heterologous protein's structure, and /or its function.

Claims 38, 39, 40, 41 and 42 are drawn to a vector and a recombinant host cell comprising the isolated nucleic acid molecule of claim 33, wherein the nucleic acid molecule is operably associated with a heterologous regulatory sequence that controls gene expression, a

method for producing polypeptide by the method comprising expressing the polypeptide by a cell and recovering the polypeptide. Specification on page 39-43 describes the vectors and host cells but does not indicate the function of the expressed protein.

In the instant case, the failure of the specification to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the polynucleotide (set forth in SEQID NO: 2) and the encoded protein thereby set forth in SEQ ID NO: 3 other than the fact that the polynucleotides and polypeptides of the invention are useful as reagents for differential identification of tissues (p. 10). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 3 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that does not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct. 1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-42 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description, enablement and best mode for practicing the claimed invention.

The specification is objected to because the biological material used in the claimed process is a microorganism clone, which has been deposited with American Type Culture

Association and has the accession number ATCC PTA1009. Since the clone is essential to the practice of the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the organism is not so obtainable or available, the requirement of 35 U.S.C. 112 may be satisfied by a deposit of the microorganism.

That the applicants have apparently incorporated specific references into the specification does not eliminate the issue of public availability and permanence as the vectors cited in the references and the references *per se* do not indicate, public availability of the starting materials in as much as the biological materials mentioned in a publication may be proprietary and not publicly available.

It is apparent that the claimed clone is essential to the claimed invention and the deposit is necessary for an adequate written description, enablement, and best mode for the claimed invention, because the specification lacks a specific description or demonstration of hundred percent reproducibility of the claimed protein from the deposit. Therefore because of the overlapping sequences the deposit is not 100% reproducible. Specification indicates in Example 1 (page 219, lines 771-774) that typically each ATCC deposit sample cited in Table 1 comprises a mixture of approximately equal amounts (by weight) of about 50 plasmid DNAs, each containing a different cDNA clone; but such a deposit sample may include plasmids for more or less than 50 cDNA clones, up to about 500 cDNA clones. However, Example 1 only gives a generic description of isolation of a selected clone from the deposited sample, it fails to demonstrate the selection of a single clone from the mixture of cDNA clones from the deposit. Thus, the specification does not disclose a repeatable process to obtain the claimed clone from the deposit.

The specification on page 5, indicates that clone HWHQC55 (see Table 1) was deposited with American Type Culture Collection (ATCC), Manassas, VA, and was given Accession No. ATCC PTA1009. The deposit was made under the terms of Budapest Treaty on the international recognition of the deposit of microorganisms for purposes of patent procedure. However Applicants fail to provide a receipt for the certificate of deposit. It is apparent that the claimed deposit material is essential to the claimed invention and the deposit is necessary for an adequate written description and enablement for the claimed invention. Applicants should provide a

photocopy of the receipt of the certificate of deposit. The Office notes that during the pendency of this application, access to the invention will be afforded to the Commissioner upon request where all restrictions upon availability to the public will be irrevocably removed upon granting of the patent and that the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer where the deposit will be replaced if it should ever become inviable.

Claim 33-42 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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